MINUTES

Utah Department of Health
Drug Utilization Review Board

Thursday, December 14, 2017
7:15 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

Board Members Present:
Ben Berrett, Pharm.D.
Jennifer Brinton, M.D.
Eric Cannon, Pharm.D., FAMCP
Neal Catalano, Pharm.D.
Steve Lore, M.D.
Kim Michelson, D.D.S.
Kumar Shah, M.Sc., P.Eng.
Susan Siegfreid, M.D.
Katherine Smith, Pharm.D.
Keith Tolman, M.D., Board Chair
Sharon Weinstein, M.D.

Board Members Excused:
Aesha Drozdowski, Pharm.D.

Dept. of Health/Div. of Health Care Financing Staff Present:
Robyn Seely, Pharm.D., DUR Manager
Bryan Larson, Pharm.D., P&T Manager
Andrea Rico, CPhT
Merelynn Berrett, R.N.
Alyssa Pitts, R.N.

University of Utah Drug Regimen Review Center Staff Presenter:
Joanne LaFleur, University of Utah Drug Regimen Review Center (DRRC)
Valerie Gonzales, DRRC
Joanita Lake, B.Pharm, MSc EBHC
Elena Martinez Alonso, DRRC

Other Individuals Present:
Kaysen Baca, Biogen
Scott Clegg, Lilly
Lori Howarth, Bayer
Patrick Moty, Horizon Pharma
Lisa Wilson, Biogen

Meeting conducted by: Board Chair

1. **Welcome:** Keith Tolman opened the meeting and announced a quorum.

2. **Information:** Keith Tolman mentioned national budgetary activity as it pertains to national CHIPs. He mentioned the following new drugs: CA-008 (analgesic), ABXS-101 (spinomuscular atrophy treatment), and Abilify Mycite (aripiprazole with an ingestible Event Marker).

3. **Review and Approval of November Minutes:** Kumar Shah motioned to accept the minutes as presented. Eric Cannon seconded the motion. Unanimous approval.

4. **Pharmacy and Therapeutics Committee Meeting Update:** November's topic was DPP4 inhibitors. There will be no meeting in December. January's topic will be antiplatelet agents.

5. **Orphan Drugs: A High-Level Review, Emphasizing Carbaglu:**

    a. **Review:** Valarie Gonzalez presented a review of orphan drugs, including their definition, their clinical utility, and manufacturer incentives in place to encourage development of orphan drugs.

    b. **Carbaglu (carglumic acid):** Valerie Gonzalez specifically discussed Carbaglu, a treatment for n-acetylglutamate synthase (NAGS) deficiency. She mentioned peer-reviewed research, clinical trials, and disease-state treatment guidelines, noting that the small patient population limits data collection and analysis.

    c. **Public Comment:** Keith Tolman read aloud from email communications between himself and Nickola Longo, MD, medical and pediatric genetics specialist.

    d. **Board Discussion, Carbaglu:** Valarie Gonzales re-iterated side-effects, contraindications, and off-label uses for Carbaglu, upon request. Treatment often begins in the inpatient setting to neonates, before genetic testing can be completed. Specialists must be consulted. Steve Lore would like more data, but there is only one Utah Medicaid patient taking Carbaglu, so we can't expect more data. Specialists must initiate treatment before non-specialists take over treatment. The Board considered requiring a trial of Carbaglu as soon as tentative diagnosis is made (often immediately after birth, in the inpatient setting), while waiting for genetic testing. The Board considered requiring prior authorization only after three months, when genetic testing can be expected back.

    e. **Carbaglu Motion:** Jennifer Brinton: outpatient treatment should be initiated by a health care provider who specializes in metabolic disorders. After initiation, treatment can be taken over by PCP, with a specific plan for continued treatment developed in conjunction with the specialist. Second: Kim Michelson Unanimous approval. Note: Sharon Weinstein left the meeting before a vote was taken.

    f. **Public Comment:** Kaysen Baca, Biogen, spoke regarding Spinraza. Keith

Tolman suggested holding his comments until Spinraza is specifically discussed at a later meeting. Kaysen Baca agreed.

g. **Board Discussion, Orphan Drugs**: Kumar Shah observed that treatment must be individualized. Jennifer Brinton pointed out that there are two items under discussion; possible PA criteria for Carbaglu specifically, and for Orphan drugs generally. Eric Cannon observed that for most orphan disease states, care can be taken over by a primary care provider after a specialist initiates treatment, if proper treatment can be assured.

h. **Orphan Drugs Motion:** Steve Lore: outpatient treatment should be initiated by a health care provider who specializes in "x" [the particular disease state]. Treatment can be taken over by PCP, with a specific plan for continued treatment developed in conjunction with the specialist. Second: Ben Berrett, Susan Siegfreid abstained, otherwise unanimous approval. Note: Sharon Weinstein left the meeting before a vote was taken.

6. **Public Meeting Adjourned:** Kumar Shah motioned to close the meeting Steve Lore seconded the motion. Unanimous approval.

7. **The next meeting scheduled for** Thursday, January 11, 2018

Audio recordings of DUR meetings are available online at:
https://medicaid.utah.gov/pharmacy/drug-utilization-review-board?p=DUR%20Board%20Audio%20Recordings/